

REMARKS

The undersigned wishes to thank Examiner Willse for a courteous and productive telephonic interview on August 11, 2011. During the interview, certain claim changes shown above were discussed vis-à-vis the sole cited reference, U.S. Patent No. 5,957,977 to Melvin ("Melvin"). General agreement as to subject matter was reached, if not specific agreement on claim language, pending this submission.

In the interview summary from August 12, 2011, Examiner Willse suggested looking to the response to the Office Action of January 29, 2004 for claim changes in view of Melvin. The claims were changed at that time to distinguish the "passive" system claimed and the "active" system of Melvin. A similar distinction is made herein, and thus Applicants believe the essence of the previous amendment has been incorporated.

Initially, the undersigned is unsure whether the proper priority claim has been made, and out of an abundance of caution has provided one.

Also, a statement of incorporation by reference has been updated with the corresponding patent number.

Claims 60-62, 64, 66-68, and 83-88 were pending, with claims 1-59, 63, 65, 69-82, and 89-98 having been previously canceled. Claims 60-62, 64, 66-68, and 83-84 are canceled herein, and claims 99-126 are added. Therefore claims 85-88 and 99-126 remain pending.

Claims 60-62, 64, 66, 67, 83, and 84 stand rejected under 35 U.S.C. §102(e) as being anticipated by Melvin. Melvin discloses an activation device for the heart including internal and external support structures. The internal structures include a first ring 56 for the mitral annulus, a second ring 58 for the aortic annulus, and a triangular frame 53 with septal splint 54 intended to be positioned against a septal wall within one of the ventricles. The external structures include a yoke 70 and an "activator 74" that pneumatically or hydraulically massages a ventricular apex to cause changes in volume of the corresponding chamber (see col. 7, lines 4-24).

The internal and external support structures are connected together and as a group act to stabilize the "skeletal" portions of the heart while the activator 74 pumps the ventricle. For instance, the septal splint 54 (triangular frame 53 with strands of sutures affixed thereto) forms a "tennis

racket-like shaped configuration to brace or stabilize one side of the interventricular septum without distortion of the chordae.” (col. 5, lines 10-15) Also, the “first and second rings 56 and 58 and septal splint 54 are attached to each other using connectors 59, such as a pin to assist in maintaining the relative position so that the first and second rings 56 and 58, respectively, and the splint 54 are supported while the natural heart 10 is being activated. ” (col. 5, lines 18-20) as seen in Fig. 2. Additionally, a plurality of cords 86 (Fig. 2) connect the internal and external structures through the walls of the heart, and “spacing of the cords 86 should preferably be at intervals of between 15 mm to 20 mm along the yoke 70, from the septal splint 54 and the first ring 56 extending obliquely outward toward the left ventricle exterior wall for insertion into the left ventricle margin of the yoke 70.” (Sentence spanning cols. 5-6) Finally, the “generally stirrup shaped yoke 70 restricts free motion of the natural heart 10 so that the natural heart 10 can be activated.” (col. 5, lines 35-37)

Independent claims 85 and 87 have been amended to further distinguish the device in Melvin. First, both claims include passive devices secured to the in situ mitral valve that passively treat the mitral valve. The Melvin device is anything but passive, with the internal and external structures providing support for the obviously active activator 74 that massages the ventricle. Secondly, the claims have been clarified to provide direct tension between at least one (claim 85) or two (claim 87) papillary muscles and a ring of the passive device at the mitral valve. Melvin discloses cords 86, but those extend from the first (mitral) ring 56 “obliquely outward toward the left ventricle exterior wall.” As seen in Fig. 2, the cords 86 attached to the first ring 56 are relatively short and appear to extend outward, not toward the ventricle. Also, they connect to the external yoke 70, not to a papillary muscle in the ventricle. Furthermore, in claim 85 first and second anchoring structures to which the first end second flexible elongate members secure are discrete, whereas the cords 86 of Melvin extend from the internal structures to a common yoke 70. Consequently, Applicant believes that independent claims 85 and 87 are allowable over Melvin, and such determination is respectfully solicited.

Existing and new dependent claims provide additional features not shown or suggested in Melvin. For instance, Melvin does not disclose a transverse flexible elongate member across the

Serial No.: 09/981,790
Docket No.: ECV-6142C
RCE-Amendment dated September 12, 2011
Response to FINAL Office Action dated April 12, 2011

ventricular cavity and between first and second anchors of the flexible elongate members, such as shown in Fig. 9. Numerous other examples could be cited.

The new claims do not add new matter. Some of the new claims do not read on the species elected on January 22, 2003, and have been introduced as “New-Withdrawn” accordingly. If a different identifier is required, please let us know.

Applicant asserts therefore that claims 60-62, 64, 66-68, 85-88 and 99-126 as amended are in condition for allowance, and respectfully requests such action.

Respectfully submitted,

Date: September 12, 2010

/Guy Cumberbatch, Reg. No. 36,114/
Guy Cumberbatch, Reg. No. 36,114
(805) 201-3006
c/o AnneMarie Kaiser, Reg. No. 37,649
Edwards Lifesciences
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-2574
Facsimile: (949) 250-6850